REMARKS/ARGUMENTS

Claims 26, 28-32, 35-43, 45-49, 51, 52, 54, 55, 57 and 61 are pending in the application. All of these claims are rejected. In this Response, claims 26, 43, 46, 49 and 52 are amended and claims 29, 40-42, 47-48, 54, 57 and 61 are canceled without prejudice or disclaimer. The claim amendments are entirely supported by the application as filed and thus there is no issue of new matter. Entry of the amendments into the file of the application is respectfully requested. Upon such entry, claims 26, 28, 30-32, 35-39, 43, 45-46, 49, 51-52 and 55, as amended, will appear in the application for the Examiner's consideration,

Claim Rejection Under 35 U.S.C. 112, First Paragraph

The Examiner continues to maintain the rejection of claims 57 and 61 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement. Although the associate respectfully disagrees with the Examiner's position, in an effort to advance the prosecution of this application the subject claims are canceled herein without prejudice or disclaimer. This is believed to render the rejection moot. It should, therefore, be withdrawn.

Claim Rejection Under 35 U.S.C. 112, Second Paragraph

In a new ground of rejection, claims 26, 28-32, 35-43, 45-49, 51 and 57 are rejected under 35 USC, second paragraph. The Office Action points out (see, e.g., p. 3) that in independent claims 26 and 43, the value of variable "R1" in formula (l) is not defined.

In response to this ground for rejection, claims 26 and 43 have been amended so as to define the value of R1. These amendments are believed to overcome the rejection under §112, second paragraph, which should therefore be withdrawn.

Claim Rejection Under 35 U.S.C. §102

Claims 43, 45-49, 51 and 57 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Zbierska (Herba Polonica).

Claims 47, 48 and 57 are canceled without prejudice or disclaimer in this response. Thus, the rejection is moot as to those canceled claims. The remaining rejected claims are 43, 45, 46, 49 and 51.

Claim 43 is written in independent form, whereas claims 45, 46, 49 and 51 all depend, directly or indirectly, from claim 43. Thus the dependent claims include all of the features recited in the independent claim.

In response to this rejection, applicant has amended claim 43 such that it now recites that the chelidonine reaction product is present in water-soluble form as a salt of a strong acid. The cited reference does not disclose the feature added by amendment to claim 43. Rather, the subject reference discloses the compound N-methylchelidonine methylsulfate which is a salt of a weak acid (dimethylsulfate) and which compound is insoluble in water (see, e.g., p. 311, last paragraph).

Since the subject reference does not disclose every feature of the claimed composition recited in claim 43 as amended, the subject claim is not anticipated thereby. Furthermore, since the dependent claims 45, 46, 49 and 51 all contain the same features as recited in claim 43, those claims are also believed to be distinguishable over the subject reference for the same reasons as claim 43.

The Examiner is, therefore, requested to reconsider and withdraw the anticipation rejection of applicant's claims under 35 U.S.C. 102.

Claim Rejection Under 35 U.S.C. §103

Claims 52, 54, 55 and 61 are rejected under 35 U.S.C. 103 as being allegedly unpatentable over Zbierska (Herba Polonica).

Claims 54 and 61 are canceled without prejudice or disclaimer in the present Response. Thus the rejection is moot as to the subject claims. The remaining rejected claims are, therefore, independent claim 52 and dependent claim 55.

Claim 52 is amended in this Response to recite, *inter alia*, that R1 is a hydrogen, or a methyl or ethyl residue and that the chelidonine reaction product is present in water-soluble form as a salt of a strong acid, wherein the chelidonine reaction product is useful as a drug or a medicament. As claim 55 is dependent upon claim 52, it too contains all of the features recited in the independent claim.

The Zbierska reference discloses anti-cancer properties of the compound N-methylchelidonine methylsulfate, which (as noted above) is the salt of a weak acid, i.e., of dimethylsulfate and which is not soluble in water, ether or chloroform (see, e.g., p. 311, last

paragraph). The reference discloses that for analytical purposes the compound was dissolved in DMSO, which is an organic solvent (see p. 312, lines 18-20 of the reference). The anti-cancer properties were tested *in vitro* and *in vivo* in mice.

Claim 52 is distinguishable from Zbierska in that it recites a chelidonine reaction product that is present in water soluble form as a salt of a strong acid, such as a hydrochloride, i.e., as recited in claim 55. The technical effect of using the salt of a strong acid, instead of using a salt of a weak acid, as taught in Zbierska, is that the presently claimed reaction product is water-soluble and is, therefore, particularly suitable in forming injectable solutions for medical applications in humans (see, e.g., p. 5, lines 16-17 of the corresponding International Publication No. WO 2004/082698). More specifically, due to the difference described above, the presently claimed chelidonine reaction product produces a less toxic, injectable pharmaceutical composition having a reduced risk of causing adverse effects, i.e., in contrast to preparations which include the 'state of the art' material, i.e., N-methylchelidonine methylsulfate.

There is no teaching, or even a suggestion to be found in Zbierska to substitute the salt of a strong acid for the salt of a weak acid as taught therein, nor that such a substitution would reduce toxicity when the material is used in medical applications or, for that matter, that such a material as presently claimed could be suitable for medical applications at all.

Due to the fact, therefore, that the reaction product as now claimed and the compound described in the cited Zbierska reference are neither structural homologs, nor share similar chemical properties, the applicant respectfully submits that the composition now recited in (amended) claims 52 and 55 is not obvious over the disclosure contained in the prior art. It certainly would have not been obvious to one having at least an ordinary level of skill in the relevant field to prepare the presently claimed chelidonine reaction product with the expectation of obtaining a compound having a pharmacological, e.g., anti-cancer, activity. Thus, for the reasons presented above, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. 103 of applicant's claims 52 and 55.

Summary

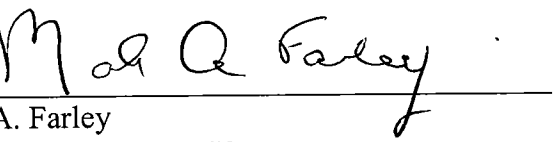
The claim amendments and arguments set forth herein are believed to be sufficient to overcome all of the grounds for rejection set forth in the pending Office Action regarding this application. The Examiner is, thus, respectfully requested to reconsider and withdraw all such

rejections and to issue a Notice of Allowance for the remaining claims (as amended) contained in this application.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON October 20, 2009.

MAF:stb

Respectfully submitted,



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